DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
301 M3545 Fax

60 8th Street, N.E.
Atlanta, Georgia 30309

October 13, 1999

VIA FEDERAL EXPRESS

William C. McMillan
President
Ultralite Enterprises, Inc.
390 Farmer Court
Lawrenceville, Georgia 30045

WARNING LETTER
(00-ATL-3)

Dear Mr. McMillan:

An inspection of your firm was conducted on September 15-20, 1999, by Investigator Fulton A. Varner. Our investigator found that you were manufacturing phototherapy chambers. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture and distribute to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to establish and maintain appropriate procedures for acceptance of all incoming components currently used in your device. You have failed to properly validate the software currently used to control the radiation dose a patient receives and to measure the accumulated dose a patient receives. None of the software utilized in these programs has been validated to assure that it functions properly. No assessment has been conducted of the potential impact of any of the numerous changes on the functionality of the program or the effectiveness of the device. You could not provide documented evidence which established a high degree of assurance that the software revisions were effective, did not effect the safety of the device, and would allow the device to consistently meet its predetermined specifications and quality attributes. No data was available which would demonstrate the acceptability of the current software for its intended uses.

You have not established adequate formalized specifications for the UVA and UVB bulbs currently in use. The acceptance parameters for the irradiation transmittance and wavelength profiles for incoming lots of bulbs have not been established. Although Certificates of Analysis are received for these products, they are generic in nature. No lot specific charts are received which define the irradiance/wavelength profiles for any bulb received. The variance of output radiation from bulb to bulb was not known by your firm.

You have failed to establish and implement appropriate complaint handling procedures. Your complaint procedure was deficient in that it failed to assure that complaints are processed in a uniform and timely manner, complaints are evaluated for Medical Device Reporting requirements, and investigations are conducted as appropriate. A review of your current procedure found that it fails to adequately define the actions required when evaluating complaints to determine if an investigation of the adverse event should be conducted. Three patient injury complaints involving burns were listed on the Inspectional Observations (FDA 483) which lacked any follow up investigation being conducted. Any complaint involving the possible failure of a device or its labeling to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint. Any complaint that represents an event which must be reported to FDA under Part 803 (Medical Device Reporting) must be promptly reviewed, evaluated, and investigated. None of the above burn complaints were investigated and no rationale was available for this failure to appropriately respond to these complaints.

You also failed to appropriately review Service Reports to determine if they should actually be recorded and investigated as complaints. Our review of your 1998 and 1999 Service Reports found several instances that appeared to involve injuries and/or failure of your devices to meet specifications. No evaluation is conducted of the Service Reports as required and no investigation was conducted in any of these instances.

You have failed to establish and maintain procedures for implementing corrective and preventive actions. This would include analyzing complaints, service records, quality audit reports and other sources of quality data, to identify existing and potential causes of quality problems. None of the above complaints or service reports were appropriately investigated to determine the cause of the problem and did not result in any corrective or preventive action.

You have failed to adhere to your established procedures for quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Audits were conducted in 1991 and 1997 although your procedure requires that audits be conducted on an annual basis as a minimum frequency requirement. Conducting audits at intervals of six years removes an excellent source of identifying potential problem areas and negatively impacts upon an effective corrective and preventive action program. The problems noted above would raise a question as to whether all significant sources of quality data are being analyzed to identify existing and potential causes for nonconforming product or other quality problems.

You have failed to establish and maintain procedures for the identification, documentation, validation or where appropriate, verification, review, and approval of design changes before their implementation. This is to assure that any proposed changes or modification to the original design of the device will be implemented in a manner to assure that the impact of the change will be fully evaluated and documented.

You have failed to establish calibration procedures for all inspection and test equipment to assure that it is suitable for its intended purposes and is capable of producing valid results. Testing instruments used to test your devices include the [redacted] oscilloscope, [redacted] Tester, and calipers. No procedures were available which defined the calibration frequency or any maintenance requirements for these instruments. No calibration data was available for any of these instruments.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the FDA 483 was issued to and discussed with you. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 are symptomatic of underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Of particular concern is the repetitive nature of many of these observations and your firm's disregard of previous correspondence from this office. The significance of validation of the software in your devices was discussed in a letter to you after the 1991 inspection (copy enclosed). The need to validate your software was first brought to your attention in 1988. Deficiencies in your complaint handling procedure, raw material specifications, and complaint records were also pointed out during the previous inspection.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your firm's failure to contact this office or submit any type of response to the current FDA 483 is also indicative of your firm's disregard of the applicable regulations. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District

Enclosures